



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

Date: February 27, 2019

Subject: Efficacy Review for Micro-Kill Bleach Germicidal Bleach Solution EPA Reg. No. 37549-2  
(DP Barcode: 449602, E-Submission: 33122)

From: Nicole Karikari  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P) *Nicole Karikari*

Thru: Kristen Willis, Team Leader  
Product Science Branch  
Antimicrobials Division (7510P) *Kristen Willis*  
Date Signed: March 7, 2019

To: Demson Fuller, Team 32 / Wanda Henson  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: Medline Industries, Inc.  
Three Lakes Drive  
Northfield, IL 60093

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Sodium hypochlorite .....	0.65%
<u>Other Ingredients</u> .....	99.35%
Total .....	100.0%

**I BACKGROUND**

**Product Description (as packaged, as applied):** Ready-to-use (RTU) Liquid Spray

**Submission type:** Label Amendment

**Currently registered efficacy claim(s):** Hospital and healthcare disinfectant (bactericidal, virucidal, fungicidal, C. diff sporicide) for use on hard, non-porous surfaces.

**Requested action(s):** Review data supporting product registration as a disinfectant, with a 5% organic soil load present, at 30 seconds contact time for the following viruses: Cytomegalovirus, Enterovirus type D68, and Influenza B virus. Add emerging viral pathogens claims.

**Documents considered in this review:**

- Transmittal Document dated 10/8/18
- Cover Letter dated 10/8/18
- Application for Pesticide Amendment (Form 8570-1) dated 10/8/18
- Confidential Statement of Formula Basic Formulation (Form 8570-4) dated 10/31/17
- Confidential Statement of Formula Alternate Formulation 2 (Form 8570-4) dated 10/31/17
- Certification with Respect to Data Citation (Form 8570-34) dated 10/8/18
- Data Matrix (Agency and Public Copies) (Form 8570-35) dated 10/8/18
- Product Label Version 1 (Clean and Redline Versions) dated 10/8/18
- Product Label Version 2 dated 12/5/2018
- Three Efficacy Studies
  - MRID 50631801 dated 5/3/18
  - MRID 50631802 dated 4/10/18
    - Amended study report dated 2/19/19
  - MRID 50631803 dated 4/10/18
- Certification of Analysis dated 2/5/18

**II PROPOSED DIRECTIONS FOR USE**

“1. Always use personal protective equipment.+

2. Open [Product Name] [container]. [Replace the closure with the trigger sprayer.]

3. [Spray] [Apply] [Product Name] [bleach solution] on desired surface.

4. Scrub and wipe with towel of your choice over desired surface to be [decontaminated] [disinfected].

{Note: Only one of the two statements will be on the label.}

A 30 second contact time is required [for efficacy against] [to kill] [all of the] [organisms] [bacteria and viruses\*\*] on the label except a 1 minute contact time is required [for efficacy against] [to kill] [Candida albicans] [and] [Trichophyton mentagrophytes] and a 5 minutes contact time is required [for efficacy against] [to kill] Clostridium difficile spores\*. [Reapply] [Spray] [as often] as necessary to ensure that the surface remains wet for the entire contact time.

OR

Allow treated surfaces to remain thoroughly wet for 5 minutes. [Reapply] [Spray] [as often] as necessary to ensure that the surface remains wet for the entire contact time.

5. Allow surface to air dry [and discard [used] towel[s]].”

### III STUDY SUMMARIES

<b>1.</b>	<b>MRID</b>	50631801	<b>Study Completion Date:</b>		5/3/18		
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Accuratus Lab Services, A25163					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Cytomegalovirus (ATCC VR-538), Strain AD-169					
<b>Indicator Cell Culture</b>		MRC-5 (human embryonic lung) cells (ATCC CCL-171)					
<b>Test Method</b>		Accuratus Lab Services Protocol #MDI01012218.CMV ( <i>copy provided</i> ), (ASTM E-1153)					
<b>Application Method</b>		Ready-to-use spray; Sprayed 6-8 inches using 3 sprays					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Micro-Kill Bleach Solution					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	MKBS LCL-1 and MKBS LCL-2					
	<b>Preparation</b>	Tested concentration: LCL Dilution: Ready-to-use Diluent: N/A					
<b>Soil load</b>		5% Fetal Bovine Serum (FBS)					
<b>Carrier type, # per lot</b>		3 glass petri dish carriers per batch					
<b>Test conditions</b>		<b>Contact time</b>	30 seconds	<b>Temp</b>	21°C	<b>RH</b>	--
<b>Neutralizer</b>		Sephadex Gel Filtration Columns					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		N/A.					

<b>2.</b>	<b>MRID</b>	50631802	<b>Study Completion Date:</b>		4/10/18		
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Accuratus Lab Services, A25163					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Enterovirus type D68, (ATCC VR-1825), Strain US/KY/14-18953					
<b>Indicator Cell Culture</b>		RD cells (ATCC CCL-136)					
<b>Test Method</b>		Accuratus Lab Services Protocol #MDI01012218.ENTV ( <i>copy provided</i> ), (ASTM E-1153)					
<b>Application Method</b>		Ready-to-use spray; Sprayed 6-8 inches using 3 sprays					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Micro-Kill Bleach Solution					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	MKBS LCL-1 and MKBS LCL-2					
	<b>Preparation</b>	Tested concentration: LCL Dilution: Ready-to-use Diluent: N/A					
<b>Soil load</b>		5% Fetal Bovine Serum (FBS)					
<b>Carrier type, # per lot</b>		3 glass petri dish carriers per batch					
<b>Test conditions</b>		<b>Contact time</b>	30 seconds	<b>Temp</b>	21°C	<b>RH</b>	--
<b>Neutralizer</b>		Sephadex Gel Filtration Columns					

<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	An amended study report was requested to address a deviation in the SOP as follows: For MRID 50631802, the Cytotoxicity Control for Batch MKBS LCL -2, 30 seconds exposure information was recorded in place of the 3 sprays application information. The number of sprays is unable to be verified. This deviation does not satisfy GLP regulations and requirements. The amended report dated 2/19/19 clarified that the SOP deviation was a documentation error and not a lab execution error and also added a GLP exemption for the documentation error.
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<b>3.</b>	<b>MRID</b>	50631803	<b>Study Completion Date:</b>	4/10/18			
<b>Study Objective</b>		Disinfectant – virucidal					
<b>Testing Lab; Lab Study ID</b>		Accuratus Lab Services, A25067					
<b>Test organism(s)</b> <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Influenza B virus, (ATCC VR-823), Strain B/Hong Kong/5/72					
<b>Indicator Cell Culture</b>		MDCK (canine kidney) cells (ATCC CCL-34)					
<b>Test Method</b>		Accuratus Lab Services Protocol #MDI01012518.FLUB ( <i>copy provided</i> ), (ASTM E-1153)					
<b>Application Method</b>		Ready-to-use spray; Sprayed 6-8 inches using 3 sprays					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Micro-Kill Bleach Solution					
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	MKBS LCL-1 and MKBS LCL-2					
	<b>Preparation</b>	Tested concentration: LCL Dilution: Ready-to-use Diluent: N/A					
<b>Soil load</b>		5% Fetal Bovine Serum (FBS)					
<b>Carrier type, # per lot</b>		3 glass petri dish carriers per batch					
<b>Test conditions</b>		<b>Contact time</b>	30 seconds	<b>Temp</b>	21°C	<b>RH</b>	--
<b>Neutralizer</b>		Sephadex Gel Filtration Columns					
<b>Reviewer comments</b> (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		N/A					

## IV STUDY RESULTS

### Non-food Contact Surface Sanitization Efficacy

#### Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results		Dried Virus Control (Log <sub>10</sub> TCID <sub>50</sub> /carrier)
			MKBS LCL-1	MKBS LCL-2	
30-seconds, RTU, 5% soil load					
50631801	Cytomegalovirus (ATCC VR-538), Strain AD-169	10 <sup>-1.3</sup> to 10 <sup>-6.3</sup> dilution	Complete inactivation	Complete inactivation	5.55
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤0.80	≤0.80	
		Log Reduction	≥4.75	≥4.75	
50631802	Enterovirus type D68, (ATCC VR-1825), Strain US/KY/14-18953	10 <sup>-1</sup> dilution	Cytotoxicity	Cytotoxicity	5.00
		10 <sup>-2</sup> to 10 <sup>-8</sup> dilution	Complete inactivation	Complete inactivation	
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤1.50	≤1.50	
		Log Reduction	≥3.50	≥3.50	
50631803	Influenza B virus, (ATCC VR-823), Strain B/Hong Kong/5/72	10 <sup>-1</sup> to 10 <sup>-8</sup> dilution	Complete inactivation	Complete inactivation	4.75
		Log <sub>10</sub> TCID <sub>50</sub> /carrier	≤0.50	≤0.50	
		Log Reduction	≥4.25	≥4.25	

## V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism	Data support tested conditions?
50631801, 50631802, 50631803	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid RTU spray; sprayed at 6-8"; apply until thoroughly wet	30 seconds	5% organic soil (v/v) Fetal Bovine Serum (FBS)	N/A	<ul style="list-style-type: none"> <li>• Cytomegalovirus (ATCC VR-538), Strain AD-169</li> <li>• Enterovirus type D68, (ATCC VR-1825), Strain US/KY/14-18953</li> <li>• Influenza B virus, (ATCC VR-823), Strain B/Hong Kong/5/72</li> </ul>	<b>Yes</b>
49456504 49486501	Emerging viral pathogens: -Enveloped viruses	Hard, non-porous surfaces	Liquid RTU spray; sprayed at 6-8"; apply until thoroughly wet	30 seconds	5% organic soil (v/v) Fetal Bovine Serum (FBS)	N/A	<ul style="list-style-type: none"> <li>• Adenovirus Type 5 [Adenovirus] [ATCC VR-5]</li> <li>• Rotavirus [ATCC VR-2018]</li> </ul>	<b>Yes</b>
49486508 50631802 49486506 49486507 49486516 49486505	Emerging viral pathogens: -Enveloped viruses -Large nonenveloped viruses -Small nonenveloped viruses	Hard, non-porous surfaces	Liquid RTU spray; sprayed at 6-8"; apply until thoroughly wet	30 seconds	5% organic soil (v/v) Fetal Bovine Serum (FBS)	N/A	<ul style="list-style-type: none"> <li>• Canine Parvovirus [ATCC VR-2017]</li> <li>• Enterovirus [Type] D68 [Strain US/KY/14-18953] [ATCC VR-1825]</li> <li>• Feline Panleukopenia Virus [Feline</li> </ul>	<b>Yes</b>

							Parvovirus] [ATCC VR-648] <ul style="list-style-type: none"> <li>• Hepatitis A Virus [(HAV)] [HM-175]</li> <li>• Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]</li> <li>• Polio Virus [Type 1] [ATCC VR-1562]</li> <li>• Rhinovirus [Type 37] [ATCC VR-1147]</li> </ul>	
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## VI LABEL COMMENTS

**Label Date/Identification Number:** December 5, 2018

1. The proposed label claims that the product, Micro-Kill Bleach Germicidal Bleach Solution, when ready-to-use as a liquid spray, is an effective disinfectant against the following organisms on hard, non-porous, non-food contact surfaces with the presence of 5% organic soil for at least 30-seconds contact time:

- Cytomegalovirus (ATCC VR-538), Strain AD-169
- Enterovirus type D68, (ATCC VR-1825), Strain US/KY/14-18953
- Influenza B virus, (ATCC VR-823), Strain B/Hong Kong/5/72

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Micro-Kill Bleach Germicidal Bleach Solution, qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to the EPA dated December 5, 2018:

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<ul style="list-style-type: none"> <li>• Avian Influenza A Virus [(H3N2)] [ATCC VR-2072]</li> <li>• Avian Influenza A Virus [(H5N1)] [CDC 2006719965]</li> <li>• Avian Influenza A Virus [(H7N9)] [CDC 2013759189]</li> <li>• Cytomegalovirus [CMV] [Strain AD-169] [ATCC VR-538]</li> <li>• Hepatitis B Virus [(DHBV)] [(HBV)]</li> <li>• Hepatitis C Virus [(BVDV)] [(HCV)] [NVS1]</li> <li>• Herpes Simplex Virus Type 2 [(HSV-2)] [ATCC VR-734]</li> <li>• Human Coronavirus [ATCC VR-740]</li> <li>• Human Immunodeficiency Virus Type 1 [(HIV-1)] [HTLV-IIIb] [Aids Virus]</li> <li>• Influenza A Virus [(Novel H1N1)] [(H1N1)] [CDC 2009712192]</li> <li>• Influenza A Virus [(Hong Kong)] [ATCC VR-544]</li> <li>• Influenza B Virus [Strain B/Hong Kong/5/72] [ATCC VR- 823]</li> <li>• Respiratory Syncytial Virus [(RSV)] [ATCC VR-26]</li> </ul>
Large, non-enveloped virus	<ul style="list-style-type: none"> <li>• Adenovirus Type 5 [Adenovirus] [ATCC VR-5]</li> <li>• Rotavirus [ATCC VR-2018]</li> </ul>



Small, non-enveloped virus	<ul style="list-style-type: none"> <li>• Canine Parvovirus [ATCC VR-2017]</li> <li>• Enterovirus [Type] D68 [Strain US/KY/14-18953] [ATCC VR-1825]</li> <li>• Feline Panleukopenia Virus [Feline Parvovirus] [ATCC VR-648]</li> <li>• Hepatitis A Virus [(HAV)] [HM-175]</li> <li>• Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]</li> <li>• Polio Virus [Type 1] [ATCC VR-1562]</li> <li>• Rhinovirus [Type 37] [ATCC VR-1147]</li> </ul>
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These claims are **not acceptable** as they are **not** supported by the cited data. Enveloped viruses are not eligible to support emerging viral pathogens claims per the [EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels](#). Large nonenveloped viruses can support a claim for an emerging enveloped virus. Small nonenveloped viruses can support claims for large nonenveloped and small nonenveloped viruses. Please revise the table on page 9 as shown below:

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<ul style="list-style-type: none"> <li>• Adenovirus Type 5 [Adenovirus] [ATCC VR-5]</li> <li>• Rotavirus [ATCC VR-2018]</li> <li>• Canine Parvovirus [ATCC VR-2017]</li> <li>• Enterovirus [Type] D68 [Strain US/KY/14-18953] [ATCC VR-1825]</li> <li>• Feline Panleukopenia Virus [Feline Parvovirus] [ATCC VR-648]</li> <li>• Hepatitis A Virus [(HAV)] [HM-175]</li> <li>• Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]</li> <li>• Polio Virus [Type 1] [ATCC VR-1562]</li> <li>• Rhinovirus [Type 37] [ATCC VR-1147]</li> </ul>
Large, non-enveloped virus	<ul style="list-style-type: none"> <li>• Canine Parvovirus [ATCC VR-2017]</li> <li>• Enterovirus [Type] D68 [Strain US/KY/14-18953] [ATCC VR-1825]</li> <li>• Feline Panleukopenia Virus [Feline Parvovirus] [ATCC VR-648]</li> <li>• Hepatitis A Virus [(HAV)] [HM-175]</li> <li>• Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]</li> <li>• Polio Virus [Type 1] [ATCC VR-1562]</li> <li>• Rhinovirus [Type 37] [ATCC VR-1147]</li> </ul>
Small, non-enveloped virus	<ul style="list-style-type: none"> <li>• Canine Parvovirus [ATCC VR-2017]</li> <li>• Enterovirus [Type] D68 [Strain US/KY/14-18953] [ATCC VR-1825]</li> </ul>

	<ul style="list-style-type: none"> <li>• Feline Panleukopenia Virus [Feline Parvovirus] [ATCC VR-648]</li> <li>• Hepatitis A Virus [(HAV)] [HM-175]</li> <li>• Norovirus [(Feline Calicivirus)] [Norwalk Virus] [ATCC VR-782]</li> <li>• Polio Virus [Type 1] [ATCC VR-1562]</li> <li>• Rhinovirus [Type 37] [ATCC VR-1147]</li> </ul>
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**Additionally**, the Terms of Registration letter should be revised to include statements 1-4 from Attachment 1 in [“EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels’”](#) as well as the revised virus table above.

3. Make the following changes to the proposed label:
  - a. Throughout the label (especially pages 1, 11-24), remove and/or revise claims with excessive bracketing. Bracketed text is treated equivalent to optional text; the label claims should still be cohesive and easy to understand when bracketed text is not included. Currently these claims are confusing and incohesive. For example, on page 1, the claim “Disinfecting solution] [This solution] [that] [is] antimicrobial, sporicidal, virucidal, bactericidal and fungicidal. [and] [can be used] [for] [on] disinfecting] [use on] hard, non-porous [environmental] [and] [healthcare] surfaces] [,] [SUGGESTED AREAS OF USAGE][.]”
  - b. Throughout the label, remove and/or revise claims with bracketing around terms such as “pre-clean” and/or state that “all gross material must be thoroughly cleaned from surfaces/objects before application of the product.” Testing with 5% soil supports one-step claims (no precleaning) for surfaces which are visibly clean. Be clear about the precleaning step which is stated throughout the label.
  - c. Throughout the label (especially on pages 5-7), remove brackets around headers and contact times. Clearly labeled sections help users to better understand the label. Therefore, header text should not be bracketed as optional. In addition, as contact time is essential for efficacy, this information should not be bracketed. Also, remove brackets around strain identifiers. This information may be separated with parentheses but is not optional.
  - d. Throughout the label (especially pages 11-31), remove statements describing dilutions of “household bleach,” “NaOCl,” and/or “sodium hypochlorite.” Concentrations of bleach can vary greatly, and this claim is not an accurate measurement of this variation. The stated dilution cannot be defined.
  - e. Throughout the label, remove all marketing claims related to “equivalent to 1:10 dilution of household bleach” or similar. This claim is misleading as there is not a defined concentration for household bleach and this product is not equivalent to a 1:10 dilution of all the variations of residential bleach products.
  - f. Throughout the label (especially pages 11-31), remove or revise “[1][one][step]”, “[one-step][cleaner]” and similar claims to state “one-step disinfectant”. One-step claims should only be associated with the contact time required to achieve disinfection.
  - g. Throughout the label (especially pages 11-31), remove all claims related to CDC, OSHA, or EPA, including webpage links. Under 40 CFR 156.10(1)(5), these claims could be interpreted as directly or indirectly implying that the pesticide is recommended or endorsed by an agency of the Federal Government.

- h. Throughout the label (especially on pages 11-31), remove “attacks” and “deactivates” as these claims could imply activity beyond what is demonstrated by the efficacy data. In addition, remove or revise “eliminate” to clearly specify the appropriate reduction (e.g. 99.9% kill) as the current claim implies complete kill. Remove “tough to kill” as this statement is relative and could be misleading for users.
- i. Throughout the label (especially pages 11-31), remove the terms “attacks”, , “deactivates”, and “tough to kill”; these terms imply heightened efficacy and are misleading.
- j. On page 2 of the proposed label:
  - i. Under the Directions for Use, state that “all gross material must be thoroughly cleaned from surfaces/objects before application of the product.” Testing with 5% soil supports no precleaning for surfaces which are visibly clean. Be clear about the precleaning step which is stated throughout the label (See comment 3b).
  - i. Under the Directions for Use, Step 4, remove “decontaminated” as this claim is typically reserved for *Bacillus anthracis* spores. Remove brackets around “[disinfected]”.
  - ii. Under the Directions for Use, Step 4, remove “[all of the]” as the inclusion of this language is too broad and could be misleading for the user. Revise statement to limit bracketing (see comment 3a).
  - iii. Under Containers, the entirety of step 1 is bracketed. See comment 3a.
- k. On pages 2, 3, and 7 of the label, revise “*Trichophyton mentagrophytes*” to “*Trichophyton interdigitale*” or “*Trichophyton interdigitale* formerly *Trichophyton mentagrophytes*” to reflect a change in designation by ATCC
- l. On page 3 of the proposed label:
  - i. Under the “Special Instructions”, remove “[all of the]” and see comment 3a.
- m. On pages 5-7 of the proposed label:
  - i. Remove brackets around headers and contact times. Clearly labeled sections help users to better understand the label. Therefore, header text should not be bracketed as optional. In addition, as contact time is essential for efficacy, this information should not be bracketed
  - ii. Remove brackets around strain identifiers. This information may be separated with parentheses but is not optional.
- n. On page 8 of the proposed label:
  - i. Revise the header of the use sites table to specify “For use on hard non-porous, nonfood contact surfaces in the following use sites:”
  - ii. In the “Use Sites Table” remove the following sites claims: “EMS”, “Environmental Services”, “General Nursing”, “Home Healthcare”, “Housekeeping”, “Infection Control”, “Nursing,” “Out Patient Care”, “Pediatrics”, “Radiology”, “Renal Dialysis”, “Respiratory Care”, and “Surgery” as these refer to actions and job titles rather than use sites. These claims are not use sites and should be removed or revised as a specific site location.
  - iii. In the “Use Sites Table” remove brackets from “Veterinarian [clinics] [hospitals]” to specify a use site.
  - iv. In the “Surfaces Table” remove “Aviation”, “Computers”, “Emergency medical services”, “Hospitality industry”, and “Law enforcement” as these claims are too vague for the “Surfaces Table” but do not belong under “Use Sites”.

- v. In the “Surfaces Table” remove brackets from “Biological safety [cabinets] [hoods]” and “Multi-module monitor [controls] [touch screens] [cables]” to specify a surface.
- vi. Remove or move “biological safety [cabinets] [hoods]”, and “pharmaceutical exhaust hoods” to the “Surfaces Table” and qualify both claims with “hard non-porous surfaces of”.
- vii. In the “Surfaces Table” remove “Janitorial surfaces” or specify the specific surfaces. This claim is confusing and vague.
- viii. In the “Surfaces Table” specify the “external surfaces” of “PCV tubing” and revise to “PVC”.
- ix. Remove “infection control” as this claim is misleading under 40 CFR 156.10(a)(5) as it could imply that the product provides health protection.
- o. On page 9 of the proposed label:
  - i. Remove “Marketing” from “Marketing Claims against Emerging Viral Pathogens. These are intended for off-label communications only. Remove brackets around the header.
- p. On page 10 of the proposed label:
  - i. Under Optional Additional Text, bullets 1-5, remove statements describing dilutions of “household bleach,” “NaOCl,” and/or “sodium hypochlorite.” Concentrations of bleach can vary greatly, and this claim is not an accurate measurement of this variation. The stated dilution cannot be defined (see comment 3d).
  - ii. For bullets 8-10, remove brackets around contact times as this information is essential for efficacy; contact time is not optional.
  - iii. For bullet 15, remove “[All in one]” as this statement is too broad.
- q. On pages 11-31 of the proposed label:
  - i. See comment 3a.
  - ii. Remove all marketing claims related to “equivalent to 1:10 dilution of household bleach” or similar. This claim is misleading as there is not a defined concentration for household bleach and this product is not equivalent to a 1:10 dilution of all the variations of residential bleach products
  - iii. Remove or revise “[1][one][-]step]”, “[one-step][cleaner]” and similar claims to state “one-step disinfectant”. One-step claims should only be associated with the contact time required to achieve disinfection.
  - iv. Remove all claims related to CDC, OSHA, or EPA, including webpage links. Under 40 CFR 156.10(1)(5), these claims could be interpreted as directly or indirectly implying that the pesticide is recommended or endorsed by an agency of the Federal Government.
  - v. Remove claims related to “effective”. This term is relative to the user’s intent, which is not always related to antimicrobial efficacy. In addition, even with the qualifier “note to reviewer: to be used with..” it is unclear how these claims will be used.
  - vi. Qualify claims against “bloodborne pathogens” with the relevant organisms from the organism list on the label.
- r. On page 11 of the proposed label:
  - i. Bullet 1 remove “attacks” and “deactivates” as these claims could imply activity beyond what is demonstrated by the efficacy data. In addition, remove or revise “eliminate” to clearly specify 99.9999% kill as the current claim implies complete kill. Remove “tough to kill” as this statement is relative and could be misleading for users.

- ii. Bullet 29 remove or revise “with one [convenient] spray” as this claim is misleading. Users should use as many sprays as necessary to thoroughly wet the surface and achieve the contact time.
- s. On page 12 of the proposed label:
  - i. Bullet 13, add “[telephone[s]] [cell] [cellular] [wireless] [mobile] [digital] phone[s]]” to the “Surfaces Table”.
  - ii. Bullet 27, remove or revise the statement, “Eliminates the need to preclean surfaces prior to disinfecting.” This claim is misleading and contradicts the statements under “Directions for Use”. Surfaces to be treated should be visibly clean, any visible soil should be removed prior to disinfection. In addition, for claims like *C. diff* spores, precleaning is required. See comment 3b.
- t. On page 13 of the proposed label:
  - i. Remove bullet 1, as this language could imply agency endorsement and “fastest contact time” could be misleading for users.
  - ii. Bullet 3 remove or revise “maximum product performance” as this could imply efficacy beyond what is demonstrated by data. In addition, efficacy was only demonstrated at room temperature – “cooler” claim should be removed.
  - iii. Bullet 16 revise such that “fecal contamination” is not linked to disinfection. Surfaces to be disinfected should be visibly clean prior to treatment.
  - iv. Bullets 25-26 remove “spread of infectious germs” and “transmission of infectious microorganisms” as these claims are misleading and imply health protection. In the statement “Helps reduce risks of cross-contamination and transmission of infectious microorganisms listed on label on hard, non-porous surfaces and [medical] equipment,” remove “transmission of infectious microorganisms.” Infection prevention cannot be claimed as this phrase suggests.
  - v. Remove the statement “No need to pre-clean when [cleaning] [and] [disinfecting].” and “No pre-cleaning [needed] [necessary] when [cleaning] [and] [disinfecting].” These statements contradict the instructions under “Directions for Use.”
- u. On page 14 of the proposed label:
  - i. Remove bullets 10-12, and 24 as these may imply endorsement by a federal agency.
  - ii. Bullets 16 and 17, the no pre-cleaning claims are potentially misleading.
  - iii. Bullet 32 remove or revise “meets AOAC efficacy testing” to “tested according to AOAC methods”.
- v. On page 15 of the proposed label:
  - i. Bullet 6 remove reference to the CFR. Reference is misleading and does not provide specific standards for glucometers.
  - ii. Bullet 10, the claim “[Product name[s]] [can be used to] [help[s]] comply[ies] with] [meet[s]] [the] [42 CFR 483.65] [for] [rigorous cleaning the environment to remove *Clostridium difficile* spores\* [,] [and can help prevent transmission of the organism],” remove and/ or revise “[rigorous cleaning the environment to remove *Clostridium difficile* spores\* [,] [and can help prevent transmission of the organism].” Remove “rigorous” as this suggests Remove “the environment;” this product is approved for cleaning of surfaces only. Remove and/ or revise “remove;” this product is approved to disinfect *Clostridium difficile* spores. Remove and/ or revise

- “transmission;” this statement implies and suggests that the product can or will prevent or control disease or offer health protection. Currently these claims could imply health protection, and they are confusing and misleading.
- iii. Bullets 3-4, 42 CFR reference is incorrect. Remove.
  - iv. Bullets 25 and 27, remove “hospital [grade]” as this claim is misleading and implies enhanced efficacy.
- w. On page 16 of the proposed label:
- i. Bullet 1, in the claim, “Reduces the risk of [infections] [and] [cross-contamination] on hard, non-porous surfaces,” remove “the risk of [infections]”. Currently this phrase implies and suggests that the product can or will prevent or control disease or offer health protection. Add “treated” before “hard, non-porous surfaces” to clearly describe approved use sites.
  - ii. Bullet 19 see comment 3.f.ii regarding “cooler” and “maximum product performance.”
  - iii. Bullet 26, in the claim “The powerful cleaning of Medline bleach,” remove “powerful”; this term implies heightened efficacy and is misleading.
- x. On page 17 of the proposed label:
- i. Bullet 8 remove or revise “antiviral” to “virucidal”. Antiviral implies health protection. Similarly, for bullet 13, remove or revise “antifungal.”
  - ii. Bullets 18 and 19, remove or revise “hospital grade” as this claim implies enhanced efficacy.
  - iii. Bullet 21 see comment 3.n. regarding removal of CFR reference.
  - iv. Remove references to OSHA and CDC as these may imply endorsement by a federal agency.
  - v. Bullets 17-23, in the statements “[This] [These] [Product[s]] [Product Name] [is] [a] [an] [are] [Ready to Use] [EPA registered] [hospital grade disinfectant] [sporicidal\*, virucidal\*\*, bactericidal, fungicidal, antimicrobial] [bleach] [solution]” and “[This] [These] [Product[s]] [Product Name] [is] [a] [an] [are] [Ready to Use] [EPA registered] [hospital grade disinfectant] [pre-diluted] [equivalent to a] [1:10 dilution of] [household bleach] [sodium hypochlorite] [solution] for [,] cleaning [,] [decontaminating] [,] [and] [disinfecting] hard, non-porous [environmental] [and] [healthcare] surfaces,” remove “hospital grade.” This term implies heightened efficacy and is misleading. Remove “1:10 dilution of” as referenced in 3.d. Remove “[decontaminate[s]] [decontaminating]” as this claim is reserved for *B. anthracis* spores.
- y. On page 18 of the proposed label:
- i. Remove the listed websites. See comment 3.g.
  - ii. Bullet 11 remove “strength of Medline[‘s]” as this may be misleading and may imply enhanced efficacy.
  - iii. Bullet 15 remove brackets. See comment 3.b.
  - iv. Bullet 16 remove “[decontaminate[s]] [decontaminating]” as this claim is reserved for *B. anthracis* spores.
- z. On page 19 of the proposed label:
- i. Remove bullet 2 as claims for infection control imply health protection. Additionally, in the statement [This product] [Product name] [solution] [can be used to] [help[s]] [to] [comply with] [make compliance with] [infection control procedures] [easier and more effective],” remove “easier and more effective.” This phrase implies heightened efficacy and it is misleading.

- ii. Bullet 3, in the claim “[Gross soil must be removed prior to disinfecting.]”, remove the brackets. Precleaning is instructed in the “Directions of Use”. This language should not be optional.
  - iii. Bullet 5, in the statement “[This Product] [Product Name] [is a] [one step] [multipurpose, broad spectrum] [bleach] [sodium hypochlorite] disinfectant [solution] that kills pathogens rapidly,” remove “rapidly” as this term is reserved for contact times of 30 seconds or less. Alternatively, qualify with organisms with 30 second contact time.
  - iv. Bullet 6 remove “recommended strength” as this claim implies endorsement and enhanced efficacy.
  - v. Bullets 7-8 remove “infectious organisms” and “protecting healthcare workers” as this language implies health protection.
  - vi. Bullet 9, in the statement “[This Product] [Product Name] [is a] [fast acting one step cleaner disinfectant] [that [cleans and disinfects] hard, non-porous surfaces quickly] [in just one step].”, remove “fast acting” and “quickly” or qualify with organisms with 30 second contact time.
  - vii. Bullet 11, in the statement [This product] [Product Name] [can be used] [use as directed] [as a one-step disinfectant on [pre-cleaned] hard, non-porous surfaces] [to disinfect] [for disinfecting] against bloodborne pathogens.”, remove the brackets from “[precleaned].” Precleaning is instructed in the “Directions of Use.”
  - viii. Bullet 12 remove or revise “eliminates the need to preclean” (see comment 3.b).
  - ix. Bullet 22 remove “attacks” and “deactivates” as these claims could imply activity beyond what is demonstrated by the efficacy data. In addition, remove or revise “eliminate” to clearly specify 99.9999% kill as the current claim implies complete kill. Remove “tough to kill” as this statement is relative and could be misleading for users. Additionally, remove excessive bracketing. See comment 3.a.
  - x. For claims related to *C. diff* spores, “in the presence of organic soil” and “after precleaning” should not be bracketed separately as this may be misleading for the user. Precleaning is required regardless.
- aa. On page 19-23 of the proposed label:
- i. Remove the phrases “eliminates the need to preclean” or revise by adding “on visibly clean surfaces” after this statement. Precleaning is instructed in the “Directions of Use” and surfaces to be treated should be visibly clean. Any visible soil should be removed before disinfection. Additionally, for specific claims, such as sporicidal claims, precleaning is a requirement.
  - ii. For claims related to *C. diff* spores, “in the presence of organic soil” and “after precleaning” should not be bracketed separately as this may be misleading for the user. Precleaning is required regardless.
  - iii. Remove all use of “attacks” and “deactivates” as these terms are misleading regarding the activity of the product. Remove “tough to kill” as this implies heightened efficacy and can be misleading.
  - iv. Remove or qualify all “eliminate” claims to ensure these claims do not imply complete kill. Claims to eliminate should not be bracketed separately from percent kill claims.
  - v. Remove claims related to “effective”. This term is relative to the user’s intent, which is not always related to antimicrobial efficacy.
  - vi. Remove or revise the phrase “hazards of cross contamination” as it could be confusing and misleading to users.

- vii. Remove or clearly revise claims such that fecal contamination is not linked to disinfection. This claim may be misleading as all visible soil should be removed from surfaces prior to disinfecting.
  - viii. Remove the term “hazards” as it could be misleading to users.
  - ix. Remove “hospital [grade]” claims as these claims may imply enhanced efficacy.
  - x. Remove “cooler” and “maximum product performance” (see comment 3.t).
- bb. On page 21 of the proposed label:
- i. Bullet 10 remove “common” as this term is vague. Refer to “Use Sites” and “Surface Table” for approved site and surface applications.

Note for PM:

Label claims stable shelf formula for 2 years. Please verify as appropriate.